

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2237051	<b>(X3) Date Survey Completed</b>  05/11/2023
<b>Name of Provider or Supplier</b>  Gray Dermatology & Cosmetic Surgery	<b>Street Address, City, State</b>  609 E Chestnut St, Lancaster, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Nurse (PN), the laboratory failed to establish and follow written policies and procedures for specimen acceptability and rejection of Mohs tissue specimens. This deficient practice had the potential to affect 100 out of 100 patients tested in the subspecialty of Histology from 02/10/2022 to 05/11/2023. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Mohs Surgery Manual" approved and signed by the Laboratory Director on 01/06/2023 found no reference to Mohs tissue specimen acceptability and rejection procedures. 2. The surveyor requested a policy and procedure for the Mohs tissue specimen acceptance and rejection including documentation from the PN on the date of the survey. The PN confirmed there was no policy and procedure or documentation for specimen rejection. The interview occurred on 05/11/2023 at 11:00 AM.</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)</p>

Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on record review, direct observation and an interview with the Practice Nurse (PN), the laboratory failed to label the secondary containers of reagents, solutions and stains in the slide stain station with their storage requirements, expiration dates, and lot numbers which were utilized for high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 100 out of 100 patients tested from 02/10/2022 to 05/11/2023. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Mohs Surgery Manual" approved and signed by the Laboratory Director on 01/06/2023 revealed the following information: "All reagents, solution, culture media, control materials, calibration materials and other supplies will be labeled to indicate: 2) Recommended storage requirements. 3) Preparation and expiration dates. 5) Other pertinent information" 2. Direct observation of the secondary containers in the slide stain station on 05/11/2023 at 11:20 AM, only found the reagent, solution or stain name and did not find each container labeled with their storage requirements, expiration dates, and lot numbers. 3. The PN confirmed the secondary containers were not labeled as required. The interview occurred on 05/11/2023 at 11:20 AM.